



DEPARTMENT OF HEALTH & HUMAN SERVICES

SEP 11 2009

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center - WO66-G609  
Silver Spring, MD 20993-0002

Ulthera, Incorporated  
% Randall E. Miller, Ph.D.  
Vice President of Clinical & Regulatory Affairs  
2150 South Country Club Drive  
Mesa, Arizona 85210

Re: K072505 Evaluation of Automatic Class III Designation  
Ulthera™ System  
Regulation Number: 21 CFR 878.4590  
Classification: II  
Product Code: OHV

Dear Dr. Miller:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your petition for classification of the Ulthera™ System indicated for use as a non-invasive dermatological aesthetic treatment to lift the eyebrow to achieve a desired aesthetic effect. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the Ulthera™ System, and substantially equivalent devices of this generic type into class II under the generic name, Focused Ultrasound Stimulator System for Aesthetic Use.

FDA identifies this generic type of device as:

Focused Ultrasound Stimulator System for Aesthetic Use is a device using focused ultrasound to produce localized, mechanical motion within tissues and cells for the purpose of producing either localized heating for tissue coagulation or for mechanical cellular membrane disruption intended for non-invasive aesthetic use.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the act), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976 (the amendments)), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and Part 07 of the FDA regulations (21 CFR 807).

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) for a device may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device type under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request classify the device type. This classification shall be the initial classification of the device type. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register classifying the device type.

On April 11, 2008, FDA filed your petition requesting classification of the Ulthera™ System into class II. The petition was submitted under section 513(f)(2) of the act. In accordance with section 513(f)(1) of the act, FDA issued an order on March 14, 2008 automatically classifying the Ulthera™ System in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, which was subsequently reclassified into class I or class II. In order to classify the Ulthera™ System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device type for its intended use.

After review of the information submitted in the petition FDA has determined that the Ulthera™ System indicated for use as a non-invasive treatment to lift the eyebrow to achieve a desired aesthetic effect can be classified in class II with the establishment of special controls. FDA believes that class II special controls provide reasonable assurance of the safety and effectiveness of the device.

In addition to the general controls of the Act, the Ulthera™ System is subject to the following special controls: the guidance document entitled, "Class II Special Controls Guidance Document: Focused Ultrasound Stimulator System for Aesthetic Use," to address the specific risks to health associated with a focused ultrasound device. The risks identified in the Special Controls Guidance Document: Focused Ultrasound Stimulator System for Aesthetic Use are: thermal injury, ocular injury, electrical shock, electromagnetic interference, inflammation/foreign body response and use error.

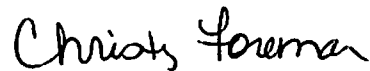
Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device and, therefore, the device is not exempt from the premarket notification requirements. Thus, persons who intend to market this device type must submit to FDA a premarket notification submission containing information on the focused ultrasound device they intend to market and receive clearance, prior to marketing their device.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market this device, subject to the general control provisions of the Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Mr. Richard P. Felten, at (301) 796-6392.

Sincerely yours,

A handwritten signature in black ink that reads "Christy Foreman". The script is cursive and fluid.

Christy Foreman  
Deputy Director  
Engineering and Science Review  
Office of Device Evaluation  
Center for Devices and  
Radiological Health